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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,761	08/24/2006	Harukazu Kitagawa	58270/A400	7304
23363 7590 12/10/2007 CHRISTIE, PARKER & HALE, LLP PO BOX 7068 PASADENA, CA 91109-7068			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,761

Applicant(s)

KITAGAWA ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>11-28-2007</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

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DETAILED ACTION

1. This Non-final Office Action is mailed in response to Applicant's request to restart the time period for response in the interview of November 28, 2007 with Applicant's representative. The prior Office Action did not provide an attached copy of a Notice to Comply as indicated in paragraph #4 below.

2. Claims 1, 4, 6 and 8 are presently pending for examination.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. There is an unbranched nucleotide sequence on page 2 of the specification as filed that was not included on the sequence listing. Additionally, there are multiple sequences on pages 4-5, and 26-27 that are not included in the sequence listing.

A complete response to this Office Action requires that Applicants comply with the sequence rules, and that pending rejections be addressed. Any response that does not address all of these issues will be held as non-responsive. Direct the reply to the

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undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (US2003091593 A1; entire document).

The instant claims recite the following:

1. An immunostimulatory oligonucleotide that comprises the following base sequence: GGGGGGGGGGACGATCGTCG (SEQ ID NO: 7).

4. A pharmaceutical formulation comprising as an active ingredient an immunostimulatory oligonucleotide comprising the base sequence: GGGGGGGGGGACGATCGTCG (SEQ ID NO: 7).

6. A pharmaceutical formulation comprising as an active ingredient an immunostimulatory oligonucleotide comprising the base sequence GGGGGGGGGGACGATCGTCG (SEQ ID NO: 7), and further comprising an immunomodulating factor.

8. A pharmaceutical formulation according to claim 6 wherein said immunomodulating factor is one of either an antigen or an adjuvant.

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Bachmann et al. discloses a formulation comprising the immunostimulatory nucleic acid G10pt mixed with VLP (virus like particles) fusion protein or VLP coupled with antigen, wherein said formulation induces a potent antigen specific CTL response and virus protection, see Figure 16, and paragraph [0055]. See also Example 12, paragraph [0341]. Example 15 describes a combination of G10pt and antigen, paragraph [0352]. The immunostimulatory nucleic acid of Bachman et al. comprises SEQ ID NO: 7 of the instant application, see the sequence below:

G10pt: **gGGGGGGGGGGACGATCGTCG**ggggggggg
 SEQ ID NO: 7: **GGGGGGGGGGACGATCGTCG**

Bachman et al. teaches all the limitations of the instant claims, and therefore anticipates the claimed invention.

7. Claims 1, 4, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (2003/0099668 A1; entire document).

8. Bachmann et al. discloses the following immunostimulatory nucleic acid molecules, which comprise SEQ ID NO: 7 of the instant application, namely nucleic acids G10-PO and G10-PS (see page 35, Table I):

g10gacga- GGGGGGGGGGGACGATCGTCGgggggggggg
PO(G10-PO)
g10gacga- ggggggggggggacgacgacgacgggggggggg
PS(G10-PS)

Example 20 of Bachmann et al. describes a vaccine formulation (see Example 20) comprising a virus like particle containing Hepatitis B virus core capsid proteins, and the G10-PS immunostimulatory nucleic acid, see Figure 50 and paragraph [0486]. This composition observed that this formulation did induce CTL responses capable of completely inhibition viral infection.

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9. Claims 1, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Takauji et al. (2002).

Takauji et al. discloses the administration of the oligonucleotide g10gacga, see page 1012, Materials and Methods §. This oligonucleotide comprises SEQ ID NO: 7 of the instant application. This reference also describes the treatment of dendritic precursor cells with g10gacga oligonucleotides and anti-IFN-a/b antibodies. Takauji et al. teach each and every aspect of the instant invention therefore anticipating the claimed invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE

Notice to Comply	Application No. 10/590,761	Applicant(s) KITAGAWA, HARUKAZU	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE
DISCLOSURES**

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: This application contains multiple sequences that are not included on the Sequence listing, see for example pages 2, 4-5, and 26-27.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification.**
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583.

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